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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,167	07/11/2000	THIERRY GICQUEL	72211/9011	6758

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,167

Applicant(s)

GICQUEL ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11, 15-17, 19-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11, 15-17, 19-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-11, 15, 17, 19-21, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 11 is rejected as vague and indefinite because the claim recites multiple vessels or sets of vessels throughout the claim; however, the claim also recites “the vessel.” As such, it is unclear if the description of “the vessel” applies to all vessels of the apparatus or just one. In addition, applicant has recited “photometric means” twice in the claim. It is unclear if the claim requires two different photometric means, or if applicant is referencing the same photometric means twice in the claim.

4. Claim 17 is rejected as vague and indefinite because the claim recites multiple vessels or sets of vessels throughout the claim; however, the claim also recites “the vessel.” As such, it is unclear if the description of “the vessel” applies to all vessels of the apparatus or just one.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Berthold et al. (US Pat. 5,290,513). The reference discloses a plurality of sample containers disposed in the form of a matrix on a holder plate. The detector of the measuring apparatus of the reference and the sample container are disposed such that the sample container being measured and the entrance window of the detector are disposed coaxially with each other. The apparatus also includes a diaphragm plate with at least one aperture, the plate being fixedly disposed between the entrance window of the detector and a sample container underneath the entrance window. There is also a component that forms a light-tight coupling between the sample container and the entrance window of the detector, and another component for pressing the sample container against the diaphragm plate (abstract). Depending on the type of luminescence reaction to be measured, the sample container may be opaque (Col. 4, lines 15-20). The device of the reference is especially suited for luminescence measurements.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
10. Claims 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,290,513) and Smethers et al. (US Pat. 5,643,535).

Uzan et al. teaches an automatic immunological assay comprising reaction wells, means for supporting samples to be analyzed, means for supporting reagents, means for taking determined quantities of samples and of reagents and depositing them in reaction wells, means for reading assay results, and means for displacing the wells (col. 1). The reference also teaches means for washing or rinsing the beads in the vessels (col. 2). Furthermore, the reaction modules are formed as single pieces by molding plastics, each comprising eight reaction wells (col. 3). In addition, the reference also teaches the use of a pivoting arm that is used to position reagents or samples (col. 5). A substrate specific to a specific enzyme in the reaction well is deposited in the well, and enzyme interaction takes place, which is followed by reading of the results (col. 7). Uzan et al. also teach horizontal plates for receiving or supporting the washing means and photometric means. The reference does not teach the specific use of vessels with opaque sides, a

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chemiluminescent substance as the enzyme in the reaction well, a shutter mechanism, or a light proof shoe.

Berthold et al. teach a plurality of sample containers disposed in the form of a matrix on a holder plate. The detector of the measuring apparatus of the reference and the sample container are disposed such that the sample container being measured and the entrance window of the detector are disposed coaxially with each other. The apparatus also includes a diaphragm plate with at least one aperture, the plate being fixedly disposed between the entrance window of the detector and a sample container underneath the entrance window. There is also a component that forms a light-tight coupling between the sample container and the entrance window of the detector, and another component for pressing the sample container against the diaphragm plate (abstract). Depending on the type of luminescence reaction to be measured, the sample container may be opaque (Col. 4, lines 15-20). The device of the reference is especially suited for luminescence measurements. However, the reference does not teach the use of a chemiluminescent substance.

Smethers et al. teach a luminometer with reduced sample crosstalk comprising an array of sample wells, a photodetector assembly, and means for moving the sample tray and photodetector (abstract). Each well in the array has a structure defining a window through which light can be emitted (col. 2). The reference also teaches the use of luminescence, either chemiluminescence or bioluminescence, as an effective for the determination of a variety of analytes (col. 1). Smethers et al. also teach a photodetector internal-calibration system. This includes a sealed chamber with a light source contained therein, a photosensor, and means for directing the light emitted from the light source to the photodetector when the assembly is

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positioned at an internal calibration system station. In addition, the reference teaches an external calibration system (col. 2).

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the opaque vessel and light-proof shoe of Berthold et al. and the chemiluminescent label of Smethers et al. with the vessel of Uzan et al. One would have been motivated to use a chemiluminescent label with the vessel of Uzan et al. because they teach the generic use an enzyme specific for a substrate that produces a detectable signal. In addition, Berthold also generically teaches the detection of luminescence. Chemiluminescent labels are widely used for this purpose, and would have been an obvious choice for use in the vessel. In addition, one would have been motivated to use a vessel or well with opaque sides to reduce the cross talk or contamination of reading between cells. Since opaque sides limit the emission of light to the top-filling opening, other wells will not be contaminated with the results of adjacent wells. It would have further been *prima facie* obvious to one of ordinary skill at the time of the invention to use the lightproof shoe of Berthold et al. with the vessel of Uzan et al. because such an arrangement limits the entrance of ambient light and prevents contamination from other sources, such as adjacent sample containers.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,290,513) and Smethers et al. (US Pat. 5,643,535) as applied to claims 17 and 19-20 above, and further in view of Honzawa et al. (US Pat. 5,637,874).

Uzan et al., Berthold et al., and Smethers et al. teach a modified apparatus, as previously Discussed. However, the references do not teach a shutter mechanism.

Honzawa et al. teach a chemiluminescence measuring apparatus comprising a shutter mechanism. The shutter mechanism, when closed, will create a temporary dark chamber that is proof against external light, at which time the photodetector will measure the luminescence. Furthermore, the shutter mechanism includes a rotating hollow chamber, which houses the vessel, a dark box, that encompasses the read window, and a photosensing unit, which includes a photomultiplier (col. 2). The rotation of the cylindrical member determines when the shutter opens and closes, and correspondingly when the luminescence is measured. In addition, the dark box portion has an opening that creates an optical path between the vessel and photometric means (col. 2).

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the shutter mechanism of Honzawa et al. with the modified vessel of Uzan et al., Berthold et al., and Smethers et al. One would have been motivated to use the shutter mechanism to create a temporary dark chamber to obtain a luminescence reading. Furthermore, a shutter mechanism is well known in the art, as the majority of commercially available photometry instruments utilize these mechanisms to take luminescence readings.

Allowable Subject Matter

12. Claims 6-11, 15, and 23 are allowable over the prior art of record.
13. Claims 6-11 and 15 are allowable over the prior art of record for reasons discussed in the Notice of Allowance mailed on May 3, 2002, and claim 23 is allowable because the prior art does not teach a method of assay comprising all the steps of the claim.
14. Claims 6-11, 15, and 23 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

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Response to Arguments

15. Applicant's arguments with respect to claims 6-11, 15-17, 19-21, and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 6-11, 15-17, 19-21, and 23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



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03/07/05